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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,534	05/31/2000	BARBARA ENSOLI	11340-003-999	9400

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER

STUCKER, JEFFREY J

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,534

Applicant(s)

ENSOLI, BARBARA

Examiner

Jeffrey Stucker

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 124-126, 169-178 and 192 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-123, 127, 128, 142-168, and 179-191 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/13/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

This Office Action is in response to the amendment filed 12/13/05.

Claims 64, 67, 70-88, 104, 113, 115, 118, 120, 129-141 are canceled.

Claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-128, and 142-192 are pending.

Claims 124-126, 169-178, 192 are withdrawn from consideration.

Claims 62, 63, 65, 66, 68, 69, 89-103, 105-112, 114, 116, 117, 119, 121-123, 127, 128, 142-168, and 179-191 are examined and under final rejection.

It is noted that Applicant's summary of the pending claims on the tops of page 12 of the response is incorrect.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Applicant's information disclosure statements are acknowledged. The new IDS filed 12/13/05 has been considered.

The second IDS, which is a copy of a 23 page IDS filed 11/17/00, as per the enclosed copy of the postcard receipt, has been reviewed and has been found to be not in compliance with

Art Unit: 1648

the required content of an information disclosure statement under the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. Applicant's attention is drawn to 37 CFR 1.98.(b)(5) (Content of information disclosure statement):

(b)(5) Each publication listed in an information disclosure statement must be identified by publisher, author (if any), **title**, relevant pages of the publication, date, and place of publication. [emphasis added]

Please note that the form 1449 lacks titles for all of the references cited.

Applicant is urged to be a little more diligent in reviewing the file for missing papers. Finding a 23 page IDS five years after it was filed does not make for efficient, compact, prosecution. Even though this IDS is not in compliance, solely to expedite prosecution so long after the filing, the cited references have been reviewed and considered but the 1449 has not been initialed due to its lack of compliance with 37 CFR 1.98.(b)(5). A new copy of the 1449 originally filed 11/17/00 (containing only the same references) in compliance with the rules will be initialed and dated.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 128, and new claims 142-150, 152, 153, 155-159,

Art Unit: 1648

161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. § 102(b) as being anticipated by Chang et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang's composition does not teach or suggest each and every element of the claimed invention because Chang does not disclose a composition that is suitable for human administration. Applicant's standard for "suitable for human administration" is argued to be the criteria promulgated by agencies such as the FDA or the EMEA. Applicant's evidence of the foregoing is a 37 CFR § 1.132 declaration by Dr. Gad (Gad declaration).

The reference is, as stated by Applicant, silent on the type of HPLC purification that was used. Applicant relies on the disclosures of earlier references to posit that Chang used reverse phase HPLC. Applicant goes even further, and just plain out speculates as to the solvents used by Chang. Applicant asserts that because acetonitrile is commonly used, it must have been used in Chang. One could also assert, very reasonably, that because the eluted protein is intended to be used as an immunogen, the authors would have used the least toxic approach possible. Turning to the Gad declaration, it is noted that the relevant portions of the declaration are not within the direct knowledge of Dr. Gad. For example, in the first line of ¶ 4, "I

Art Unit: 1648

am informed that a solvent commonly used for reverse phase HPLC is acetonitrile..." He clearly does not know how the procedure in question was performed and does not state who informed him of what is commonly used. Later in the same paragraph, he is "assuming use of a solvent containing acetonitrile" and "the foregoing understanding". These types of phrases further indicate that he is working with the speculation provided by others. With all due respect to Dr. Gad, his expertise lies in toxicology and the Office is not disputing his conclusions about the toxic effects of various chemicals. However, Dr. Gad cannot speak to how the Chang Tat was purified. Therefore, this declaration is not convincing.

As Applicant points out at page 16 of the response, Chang teaches two different methods of purifying Tat. The second method is not relevant to the instant discussion because the first method is directed to producing the antigen for injection. Turning to the 37 CFR § 1.132 declaration by Dr. Ensoli, this declaration is likewise not convincing. For instance, Dr. Ensoli at ¶ 5 states that "it is my opinion that..." how various purification steps would be performed by one of ordinary skill in the art and "it is my opinion" that the eluted Tat protein would be tainted with HPLC buffer. Like Dr. Gad, Dr. Ensoli apparently cannot state what solvents were used or in what

Art Unit: 1648

order. In ¶ 6, Dr. Ensoli notes what is commonly used and cites several reference books on the subject. She states in the last line that a buffer containing acetonitrile and TFA was used. However, it is not clear if this is a conclusion based on the disclosures of the cited books extended to the instant invention or a statement within her knowledge based on her co-authorship of the Chang, Ensoli, and Bohan references. The declarations based on opinion and speculation are not convincing, particularly when such information is within direct knowledge of the inventor/declarant.

Even if there was a convincing showing that acetonitrile, TFA, etc, were indeed in the final composition, Applicant's standard that current FDA or the EMEA criteria must be met, is not the standard for the PTO. The Office is not the FDA (or EMEA) and does not use the same standards. The prior art merely has to work, not be perfect. It remains the Office position that the composition of Chang anticipates the claimed invention and is suitable for the administration to humans.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 114, 119, 128, and new claims 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185, 186 and 189 under 35

Art Unit: 1648

U.S.C. § 103(a) as obvious over Chang et al. in view of Heiman et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Heiman does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning Chang are noted but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instantly claimed invention is obvious over Chang et al. in view of Heiman et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-95, 97, 101-103, 105-111, 116, 117, 121, 122, 128, and new claims 142-168, 179-187, 190, and 191 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Vogel et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Vogel does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning Chang are noted

Art Unit: 1648

but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instantly claimed invention is obvious over Chang et al. in view of Vogel et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 99, 106, 107, 128, and new claims 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Castignolles et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Castignolles does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning Chang are noted but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instantly claimed invention is obvious over Chang et al. in view of Castignolles et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 100, 106, 107, 128, and new claims 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. §

Art Unit: 1648

103(a) as obvious over Chang et al. in view of Ramshaw et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Ramshaw does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning Chang are noted but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instant invention is obvious over Chang et al. in view of Ramshaw et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 112, 128, and new claims 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185, 186, and 188 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Livingston et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Livingston does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning

Art Unit: 1648

Chang are noted but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instant invention is obvious over Chang et al. in view of Livingston et al.

The rejection of claims 62, 63, 65, 66, 68, 69, 89, 90, 93-94, 106, 107, 123, 128, and new claims 142-150, 152, 153, 155-159, 161, 162, 164-168, 179-183, 185 and 186 under 35 U.S.C. § 103(a) as obvious over Chang et al. in view of Barry et al. is maintained.

Applicant's arguments have been fully considered but are not deemed to be persuasive. Applicant argues that Chang does not teach or suggest a biologically active Tat protein in a form suitable for administration to humans as recited in amended claim 62 and that Barry does not cure the alleged deficiency of Chang. Applicant's prior arguments concerning Chang are noted but are not convincing for the reasons given above and the Chang rejection is maintained. Thus, the instantly claimed invention is obvious over Chang et al. in view of Barry et al.

No claims are allowed.

Art Unit: 1648

THIS ACTION IS MADE FINAL. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Official Fax number is: (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1648

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (571)-272-0911. The examiner can normally be reached Monday to Thursday from 7:00am-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571)-272-0902.


JEFFREY STUCKER
PRIMARY EXAMINER

Continuation of Disposition of Claims: Claims pending in the application are 62,63,65,66,68,69,89-103,105-112,114,116,117,119,121-128 and 142-192.